REMARKS

In the foregoing amendments, claim 27 was amended to define that the black currant anthocyanin-containing food composition suitable for human consumption contains not more than 5 % by weight organic acid on the basis of solid matters, and that monosaccharide is not essentially found. Claims 35, 36, 38 and 40 were amended by deleting the expression "health-promoting." Claim 30 was amended to depend from claim 27. In claims 37 and 39, the limitations defining visual function were set forth in a Markush grouping. A similar amendment was made to claim 40. Other minor editorial changes were made to applicant's claims.

Claims 42-49 were added to the application. New independent claims 42 and 46 set forth amounts of black currant anthocyanin and an organic acid along the lines set forth in amended claim 27. New claim 46 defines a black currant anthocyanin-containing concentrated solution suitable for human consumption. New claims 43 and 47 define amounts of delphinidin and delphinidin-3-o-rutinoside along the lines set forth in claims 28 and 29. New claims 44 and 48 are product-by-process claims that include the limitations of claim 30. New claims 45 and 48 further define that monosaccharides are essentially not contained. New claim 49 defines that the black currant anthocyanin-containing concentrated solution is further processed into a form of a member selected from the group consisting of a paste, gel and powder, such as described on page 21, lines 4-6, and in examples 1 and 2 of applicant's

specification disclosure. Accordingly, claims 27-30, 32-40 and 42-49 are present in the application for consideration by the examiner.

The Official action totaled 15 pages. Applicant begins with a discussion of the prior art rejections. The Official action set forth two prior art rejections of applicant's claims. Claims 30 and 32-34 were rejected under 35 U.S.C. § 103(a) as being unpatenable over U.S. patent No. 4,643,902 of Lawhon (Lawhon). This rejection is set forth on pages 7 and 8 of the Official action. Claims 27-29 and 35-41 were rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, as obvious under 35 U.S.C. § 103(a) over Lawhon in view of Nakhmedov[1] *et al.* (Konservanaya I Ovoshchesushil'naya Promyshlennost) (hereinafter referred to as "Nakhmedov) and British patent specification number 1,007,751 (British '751). This rejection as set forth on pages 8-10 of the Official action. These rejections are similar to those previously set forth. On pages 11 and 14 of the Official action, additional comments concerning the prior art rejections were set forth. Applicant respectfully submits that the present claims are distinguishable from the teachings of Lawhon, Nakhmedov, and/or British '751 within the meaning of 35 U.S.C. § 102 or 35 U.S.C. § 103 for at least the following reasons.

Two issues discussed in the Official action concerning the prior art rejections were the presently claimed amounts of black currant anthocyanin and the use of a negatively charged reverse osmosis membrane. The Official

action stated that Nakhmedov proposes a quantity of anthocyanins in coloring agent produced from marc is between 5% and 6.2%, which is encompasses applicant's. The composition of claims 27, 42 and 46 comprises 5 to 25% by weight of black currant anthocyanin and organic acid content of not more than 5% by weight on the basis of solid matters. Amended claims 27, 45 and 48 further define that monosaccharide is not essentially found in the composition. In other words, the organic acid content of the compositions defined in claims 27, 42 and 46 is not more than 5% by weight on the basis of solid matters, and a monosaccharide is not essentially found in the compositions of claims 27, 45 and 48. To the contrary, Nakhmedov proposes that significant content of organic acid and sugars are contained in the coloring agent, such as shown in Table 3 therein. For such reasons, applicant respectfully submits that the teaching of Nakhmedov cannot disclose or suggest the inventions defined in claims 27, 42, 45, 46 and 48.

Foods and drinks, utilizing black currants as starting materials, have hitherto been in existence. However, those were limited to juice, alcohol beverages, jams and the like. This is because black currants contain about 20 to 30% by weight of organic acid on a solid basis and about 30 to 50% by weight of monosaccharide on a solid basis, and thus, sourness and sweetness are excessively strong. For this reason, black currants could not be extensively added to general foods. This is discussed on page 1, lines 9-17, and

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[1] Please refer to the English translation of Nakhmedov that was attached to the

elsewhere in applicant's specification disclosure. Even though black currants are added to juice, alcohol beverages, jams and the like, it was difficult to add black currants in an amount large enough to exhibit the potency of black currant anthocyanin because of the inherently small amount of the black currant anthocyanin in the black currants and strong sourness and sweetness. A main reason for this is that compositions containing a large quantity of anthocyanin free from sourness and sweetness did not exist. This has led to the strong desire for such compositions for foods containing a large quantity of black currant anthocyanin without organic acids and monosaccharide(s) in the field of food industry. The compositions of the present claims were developed to meet these needs.

Since the compositions proposed by Nakhmedov have amounts of organic acids and monosaccharide(s) in excess of that set forth in claims 27, 42, 45, 46 and 48, applicant respectfully submits that these teachings cannot contemplate or suggest the inventions defined in these claims within the meaning of 35 U.S.C. §102 or 35 U.S.C. §103. Therefore, applicant respectfully request that the examiner reconsider and withdraw any prior art rejections of the present claims that rely on the teachings of Nakhmedov.

In addition, it is respectfully noted that Table 1 of Nakhmedov is referring to marcs, the residue remaining after a fruit has been pressed (i.e., residue from the skins of the black currant berries). The quantities of

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response after final filed on April 23, 2004, in this application.

anthocyanin shown in table 1 of Nakhmedov are relative to the marks and have nothing to do with a concentrated solution of black currant juice, such as required in new claim 46.

The Official action took the position that the amounts of delphinidin and delphinidin-3-o-rutinoside in the marcs and colorants in Nakhmedov are the same as those set forth, for example, in applicant's claims 28, 29, 43 and 47. However, applicant cannot find any discussion in Nakhmedov disclosing a content of delphinidin-3-o-rutinoside. Therefore, applicant respectfully submits that it is impossible for the teachings of Nakhmedov to disclose or suggest the inventions defined in these claims.

In the rejection of claims 30 and 32-34 under 35 U.S.C. § 103(a) as being unpatenable over Nakhmedov, Lawhon and British '751, applicant previously asserted that the method of the present invention is different from Lawhon's process in that the negativity charged reverse osmosis membrane of applicant's claims fractionates compounds depending on a charge of polymer.

The outstanding Office Action stated the following:

> It is well known in the art that reverse osmosis in capable of rejecting bacteria, salts, sugars, proteins, particles, dyes, and other constituents that have a molecular weight of greater than 150-250 daltons. The separation of ions with reverse osmosis is aided by charged particles. This means that dissolved ions that carry a charge, such as salts, are more likely to be rejected by the membrane than those that are not charged, such as organics. The larger the charge and the larger the particle, the more likely it will be rejected. Since the invention of Lawhon rejects 99% NaCl, then the RO membrane disclosed in Lawhon is aided by charged particles.

However, applicant respectfully submits that the aforesaid discussion may not be correct and/or appropriate to the presently claimed invention. The RO membrane was developed for desalinating sea water to obtain fresh water. The RO membrane is placed between sea water and fresh water. When a pressure higher than the pressure of osmotic pressure is applied to sea water, water in the sea water is moved to the fresh water through the RO membrane. Since the retention rate of NaCl of the RO membrane is more than 99%, fresh water can be obtained by using the RO membrane.

To the contrary, the charged RO membrane was developed separately from the RO membrane as a nanofilter (or a loose RO membrane). The size of a substance removed by the charged RO membrane is between that of the RO membrane and ultrafiltration (UF) membrane. That is, the charged RO membrane is different from the RO membrane as a filter. In fact, the retention rate of NaCl of the charged RO membrane is 5 to 20% as disclosed in the specification of the present application at lines 13 to 16 on page 19, which is different from that of the RO membrane that is 99% or more.

Exhibit B (Chemical Engineering progress 90 (3) 68-74 (1994)) is attached hereto, which describes nanofiltration. It explains that the loose RO, low-pressure RO and ultra-osmosis membranes are all NF membranes. Some membranes designated as charged RO/UF also show similar properties and are classified here as NF membrane, from the third line from the bottom in the left column on page 68 to the third line in the right column on page 68. It also

describes "NF falls in between RO and UF in its separation characteristics (Figure 1)" at lines 12 and 13 in the left column on page 68. These descriptions clearly show that the charged RO membrane is different from the RO membrane. In Table 1 on page 69, commercially available NF membrane are listed and the list includes NTR7410 (Nitto-Denko), which was used in example 1 of the present specification. Therefore, the charged membrane described in the specification of the present application is classified into an NF membrane, not into the RO membrane.

For such reasons, any person skilled that the art would realize that the the RO membrane proposed by Lawhon is quite different and not readily changeable with the negatively charged reverse osmosis membrane defined in present claims 30, 32, 44 and 48. At least for these reasons, the RO membrane proposed by Lawhon is different from that presently claimed and cannot be readily substituted therefor, nor suggested thereby.

Exhibit A, which is attached hereto, further describes: "For example, RO membranes reject both sugars and salts, while UF membranes, on the other hand, retain sugars and certain multivalent salts (e.g., $MgSO_4$), but pass substantial amounts of most monovalent salts (e.g., NaCl)" at lines 13 to 20 in the left column on page 68. This discussion supports applicant's assertion that the substances to be fractionated are different in the process of the present invention and the process proposed by Lawhon. Namely, in the process proposed by Lawhon using a RO membrane, sugars and acids are

fractionated in RO retentate together with anthocyanin. To the contrary, the process of the presently claimed invention, by use of the negatively charged reverse osmosis membrane, retains anthocyanin in a retentate while sugars and acids pass through the membrane into a permeate. Therefore, the composition produced by the processes of claims 30, 44 and 48 is the composition in which organic acid content is not more than 5% by weight on the basis of solid matters, and monosaccharide was not essentially found.

From the above, applicant respectfully submits that the teachings of Lawhon cannot contemplate or suggest the presently claimed compositions and cannot motivate one of ordinary skill in the art to the presently claimed compositions within the meaning of 35 U.S.C. §102 or 35 U.S.C. §103. Therefore, applicant respectfully requests that the examiner reconsider and withdraw any prior art rejections of the present claim that rely on the teachings of Lawhon.

The teachings of British '751 do not cure or rectify the aforesaid deficiencies in the teachings of Nakhmedov and Lawhon. Therefore, applicant respectfully submits that all the present claims are patently distinguishable from the teachings of Nakhmedov, Lawhon and/or British '751 within the meaning of 35 U.S.C. §102 or 35 U.S.C. §103. Accordingly, applicant respectfully requests reconsideration and withdrawal of these rejections.

In the previous response, applicant explained that the use of language, such an "effective amount" including the desired property or effect has long

been recognized as acceptable in U.S. patent practice. *In re Halleck*, 164 USPQ 647, 57 CCPA 954 (CCPA 1970). The outstanding Office action responded that it is not clear whether "an affective amount" is drawn to a method claim or a composition claim. Applicant respectfully submits that the expression "an affective amount" can be used in either a composition or method claim and would be understood with precision by any person skilled in the art. Therefore, applicant respectfully requests that the examiner reconsider and withdraw the rejection under 35 U.S.C. §112, second paragraph.

On page 11 and near the bottom of page 14, the Official action commented that applicant's process claims do not reflect the differences between the retentate achieved in applicant's claimed invention and that of Lawhorn. The differences between the retentate achieved by applicant's claimed invention and that of Lawhon are achieved by the use of a negatively charged reverse osmosis membrane in the presently claimed invention. The use of the negatively charged reverse osmosis membrane provides a different composition product as defined in applicant's claims. The use of a different membrane defines a different process, because the separated materials are different and separated in a different manner. Therefore, it is not believed necessary to specifically define the retentate in the present claims. In any event, claims 44 and 48 specifically define purifying, separating and concentrating black currant anthocyanin in a retentate with a negatively

charged reverse osmosis membrane from monosaccharides and acids contained in a black currant raw material.

While the Official action commented that the product-by-process limitations in, for example, claims 30, 44 and 48 do not impart patentability to the composition itself, if the product is the same or obvious from a product of the prior art. However, the products of applicant's claims 30, 44 and 48 are not the same or obvious from any product in the prior art. For example, the marks proposed by Nakhmedov are compositions different from that of the applicant's claims; because they are not, for example, a concentrated solution made from a juice of black currant, and the marks proposed by Nakhmedov contain amounts of organic acids and monosaccharides in excess of that set forth in the present claims.

Claims 35, 36, 38 and 40 were rejected under 35 U.S.C.112, first paragraph, because the specification does not provide a written description for the conditions associated with the term "health-promoting." These claims were also rejected under 35 U.S.C. §112, second paragraph, because the term "health-promoting" in claims 35, 36, 38 and 40 is a relative term which renders the claim indefinite. In the foregoing amendments, the phrase "health-promoting" was removed from claims 35, 36, 38 and 40. Therefore, applicant respectfully submits that these rejections concerning the phrase "health-promoting" are now moot.

In the rejection of claims 35-40 under 35 U.S.C. §112, second paragraph, as being vague and indefinite, the Official action stated that the phrase "including" renders claimed 35 indefinite, because it is unclear whether the limitations following the phrase are part of the claimed invention. The examiner cited M.P.E.P. §2173.05(d). Applicant cannot understand this position. The word "including" is commonly used in claims and means that the limitations following the word "including" are part of the claimed invention. A review of M.P.E.P. §2173.05(d), which was cited in the Official action in support of this position, reveals no discussion of the word "including" therein. This portion of the M.P.E.P. discusses expressions, such as "for example," which have a meaning quite different than that of the word "including." Applicant respectfully submits that the word "including" is a common term used in patent claims that particularly points out and distinctly claimed the subject matter regarded as the invention. Therefore, applicant respectfully requests that the examiner reconsider and withdraw this rejection.

In the discussion on pages 12 and 13 of the Official action concerning the §112, second paragraph, rejection, the Official action included a long discussion concerning the "improving" expressions used in applicant's claims. Applicant does not understand the significance of the discussion concerning anticoagulant relative to applicant's claims. While the Official action questioned whether "improving blood fluidity" is desirable, applicant notes that is not necessary for the advantages of an applicant's claim to be an

improvement, but only that they are different from the prior art. In any event, the present specification disclosure explains that in recent years, the spread of life-style related diseases, attributable to opulence and lack of exercise, has come to be regarded as a problem, and particularly, matters associated with the circulatory system such as an elevated blood pressure, hyperglycemia, and an increase in neutral fat and cholesterol in blood have come to be regarded as serious. In particular, adverse affects created by neutral fats and cholesterol cause an increase in blood viscosity, thereby preventing blood from rapidly flowing through blood vessels. This increases vascular resistance which may in turn cause elevated blood pressure. It is known that, as a problem of blood cells, for example, lowered deformability of human red blood cells, an improvement in leukocyte adhesiveness, and exaltation in platelet aggregation activity lower blood fluidity. See, for example, applicant specification at lines 6 to 15 on page 11. The increase of blood fluidity causes an elevated blood pressure and so on. Thus, blood fluidity is very important for a human health. The clotting of blood for protecting the body from serious damage (injury) is associated with platelets and some clotting factors. Blood fluidity is associated with lowered deformability of human red blood cells, an improvement in leukocyte adhesiveness, and exaltation in platelet aggregation activity as well as an increase in neutral fat and cholesterol in blood and so on. The importance of the clotting of blood for protecting the body from serious damage

does not negate the importance of blood fluidity, which is achieved by the presently claimed compositions.

In the §112, second paragraph, rejection, the Official action stated that of phrases including the word "improving" in claims 37-40 render these claims vague and indefinite. The Official action included a lengthy discussion about this issue on pages 4-6, the second complete paragraph on 9, the paragraph bridging pages 10 and 11, and pages 13 and 14. The Official action stated that the term "improving visual function" in claims 37 and 38 is a relative term which renders the claim indefinite. The Official action also stated that the term "improving adaptation to darkness" is a relative term which renders the claim indefinite.

Amended claims 37 and 38 define "improving visual function selected from the group consisting of alleviating asthenopia and improving adaptation to darkness compared to adaptation to darkness before ingestion of the composition". The term "improving visual function" means "alleviating asthenopia" or "improving adaptation to darkness compared to adaptation to darkness before ingestion of the composition". Accordingly, the term "improving visual function" is defined by these claims with precision to any person skilled in the art. Therefore, applicant respectfully requests that the examiner reconsider and withdraw the rejection of the 35 U.S.C. §112, second paragraph.

Regarding the expression "alleviating asthenopia compared to asthenopia before ingestion of the composition," "alleviating asthenopia" is explained in the present specification at page 25, line 19, to page 26, line 27. Furthermore, example 3 of the present application shows the experimental data about the claimed composition that alleviates asthenopia. As demonstrated in example 3, the asthenopia was alleviated and/or improved after the ingestion of the claimed composition increased. The control subject did not ingest the composition. Example 3 clearly shows that asthenopia was alleviated and/or improved by the ingestion of the composition compared to the control subjects who did not ingest the composition.

Regarding the expression "improving adaptation to darkness compared to adaptation to darkness before ingestion of the composition," "adaptation to darkness" is explained in the present specification at lines 4 to 18 on page 25 and at lines 9 to 22 on page 27. Furthermore, example 4 of the present application shows the experimental data about the claimed composition that improves adaptation to darkness. As demonstrated in example 4, the threshold of adaptation to darkness of the subjects after the ingestion of the claimed composition increased. The control subject did not ingest the composition. Example 4 clearly shows that the threshold of adaptation to darkness increased by the ingestion of the composition compared to the control subjects who did not ingest the composition. The threshold of adaptation to

darkness of the control subject is corresponding to the threshold of adaptation to darkness of the subject before the ingestion of the composition.

For the foregoing reasons, applicant respectfully submits that any person skilled in the art would understand the expression "improving adaptation to darkness" as set forth in the present claims with precision. Therefore, applicant respectfully requests that the examiner reconsider and withdraw the rejection of the 35 U.S.C. §112, second paragraph.

The Official action stated that the term "improving blood fluidity" in claims 39 and 40 is a relative term which renders the claim indefinite. Claims 39 and 40 define "improving blood fluidity compared to blood fluidity before ingestion of the composition." The term "improving blood fluidity" is clearly defined in the specification of the present application at the second line from the bottom on page 28 to the sixth line on page 29. Example 12 of the present application demonstrates the blood fluidity improving effects. In example 12 of the present specification, the fluidity was determined by MC-FAN (Micro Channel Array Flow Analyzer). To determine the fluidity by the analyzer, a micro channel array is used as described in example 12. Please refer to Exhibit A, which is attached hereto and which is a copy of pages about MC-FAN in a web site of Hitachi Haramachi Electronics Co., Ltd. (http://www.haraden.co.jp/product/mcfan/mcfan01.html). Pages 2 and 4 of Exhibit A show the micro channel array. The width of the micro channel array is 7 μm which is the same with the diameter of blood capillary. Page 2 of

Exhibit A describes about examples of how the analyzer is used. Table 9 in example 12 clearly shows that the blood fluidity increases after ingestion of the claimed composition compared to before ingestion of the claimed composition by measuring the transit time of blood through the channel array of MC-FAN.

For the foregoing reasons, applicant respectfully submits that person skilled in the art would understand the expression "improving blood fluidity compared to blood fluidity before ingestion of the composition" as set forth in the present claims with precision. Therefore, applicant respectfully requests that the examiner reconsider and withdraw the rejection of the 35 U.S.C. §112, second paragraph.

The Official action stated that the term "lowering blood pressure" in claims 39 and 40 is a relative term which renders the claim indefinite. Claims 39 and 40 recite "lowering blood pressure compared to blood pressure before ingestion of the composition". The term "lowering blood pressure" is clearly defined in the specification of the present application at lines 22 to 27 on page 29. It describes: "As described in detail in example 12, the level of blood pressure is lowered by 5 to 8 mmHg for the maximal blood pressure and 2 to 13 mmHg for the minimal blood pressure. Example 12 demonstrates the lowering effect of blood pressure of the claimed composition.

For the foregoing reasons, applicant respectfully submits that person skilled in the art would understand the expression "lowering blood pressure" as set forth in the present claims with precision. Therefore, applicant respectfully

requests that the examiner reconsider and withdraw the rejection of the 35 U.S.C. §112, second paragraph.

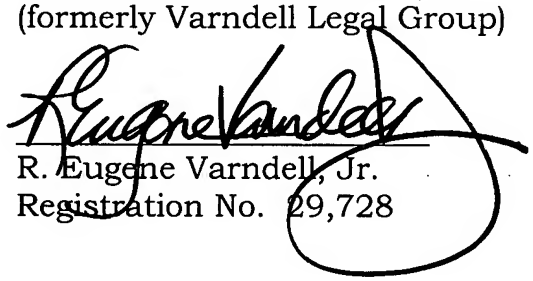
For the reason set forth above, applicant respectfully submits that the present claims particularly point out and distinctly claim the subject matter regarded as the invention within the meaning of 35 U.S.C. §112, second paragraph. Therefore, applicant respectfully requests that the examiner reconsider and withdraw this rejection.

For the foregoing reasons, applicant respectfully requests that the examiner reconsider and withdraw all the objections and rejections set forth in the Official action mailed September 9, 2005, so that all pending claims 27-30, 32-40 and 42-49 will be allowed.

While it is believed that the present application is in condition for allowance, should the examiner have any comments or questions, it is respectfully requested that the undersigned be telephoned at the below listed number to resolve any outstanding issues.

In the event that this paper is not timely filed, applicant hereby petitions for an appropriate extension of time. The Commissioner is hereby authorized to charge the fee therefor, as well as any deficiency in the payment of the required fee(s) or credit any overpayment, to our deposit account No. 50-1147

Respectfully submitted,
POSZ LAW GROUP, PLC
(formerly Varndell Legal Group)



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Attachments:
Exhibit A
Exhibit B